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IP

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/529,021 04/06/00 GLADUE R 062308.0224

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EXAMINER

WEBER, J

ART UNIT

PAPER NUMBER

1651

DATE MAILED:

03/28/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/529,021

Applicant(s)

GLADUE ET AL.

Examiner

Jon P. Weber

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: .

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Status of the Claims

Claims 1-24 have been presented for examination.

Claim Objections

Claim 10 is objected to because of the following informalities: Claim 10 recites "aparticulate" which should be two words. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 15-18 depend from claim 1, which lacks antecedent basis. It is believed that these claims should depend from claim 14.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barclay (US 5,130,242) in view of Kyle et al. (US 5,397,591) and further in view of Kilbride, Jr. et al. (US 5,000,888) and Cole et al. (US 5,104,668).

Barclay (US 5,130,242) discloses making DHA from *Thraustochytriales* by extracting the organisms with hexane, saponifying, extracting again, and low temperature fractional crystallization. The refining methods are said to be conventional in the art. Feed supplements for aquaculture, humans or poultry, for example, may be prepared by mixing the crude oil with feed. Barclay (US 5,130,242) lacks *Crypthecodinium cohnii*, spray drying, or the dried particle size.

Kyle et al. (US 5,397,591) disclose that dinoflagellates and especially *Crypthecodinium cohnii* are excellent sources of DHA-containing oil (30-40% of the tryglycerides are DHA and other components such as the polar lipids - phosphatidyl choline - are also enriched in DHA.) The DHA-containing oil is obtained by harvesting the organisms, extracting with hexane or more directly with polar solvents such as ethanol or isopropanol, and then removal of the solvent. The crude oil may be processed by conventional means in the vegetable oil processing art to allow separation of the DHA-enriched polar lipid fractions. The resulting oil may be added to infant formulas (homogenization needed) or infant foods, which are more solid in constitution.

Kilbride, Jr. et al. (US 5,000,888) disclose that it is conventional in the spray drying art to control the spray drying conditions so as to obtain a desired particle size. Conditions can be controlled for stability of the biological samples as well.

Cole et al. (US 5,104,668) disclose that it is desirable in the aquaculture art to provide feeds have a particle size in the range of 5 to 50 microns for the purpose of feeding shrimp and fish. The particles are prepared by spray drying a homogenate of the desired feedstock.

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A person of ordinary skill in the art at the time the invention was made would have been motivated to prepare DHA-containing oils from *Cryptocodinium cohnii* in dried form of 5-10 microns for the purpose of aquaculture or other feeds such as infant formula according to the teachings of Barclay (US 5,130,242) and Kyle et al. (US 5,397,591) because drying biologicals by spray drying is conventional in the art as shown by Kilbride, Jr. et al. (US 5,000,888) and because Cole et al. (US 5,104,668) show that it is known in the art that spray dried feed particles suitable for aquaculture should be from 5 to 50 microns. Providing an aqueous homogenate of the DHA-containing oil is reasonably suggested by the infant formula of Kyle et al. (US 5,397,591). The spray dried form is reasonably suggested by Cole et al. (US 5,104,668).

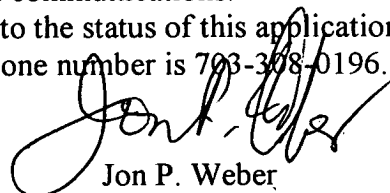
Hence, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to obtain DHA-containing oil from *Cryptocodinium cohnii* and spray dry it to form particles of 5 to 50 microns suitable for aquaculture.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon P. Weber whose telephone number is 703-308-4015. The examiner can normally be reached on 1st Fri, 9/5/4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Jon P. Weber
Primary Examiner
Art Unit 1651

JPW
March 27, 2001